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10/588,320	06/01/2007	Ralf-Christian Schlothauer	14923.0042	7221	
27890 7590 06/10/2010 STEPTOE & JOHNSON LLP			EXAMINER		
1330 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036		V.	GWARTNEY,	GWARTNEY, ELIZABETH A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/588,320 SCHLOTHAUER ET AL. Office Action Summary Examiner Art Unit ELIZABETH GWARTNEY 1781 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 03 March 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-3.6-12.14-21.23-28.30-32 and 37 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-3,6-12,14-21,23-28,30-32 and 37 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

 The Amendment filed March 3, 2010 has been entered. Claims 4-5, 13, 22, 29, 33-36 and 38 have been cancelled. Claims 1-3, 6-12, 14-21, 23-28, 30-32 and 37 are pending.

 The previous claim objections, 101, 112 1st Paragraph 112, and 112 2nd Paragraph (with respect to claims 6-17, 22-25, 29, 33-36 and 38) rejections have been withdrawn in light of applicant's amendments made March 3, 2010.

### Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 20-21 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 20, the recitations "capable of being achieved" and "optimizing" render the claim indefinite because it is not clear how the whey release is optimized.

Regarding claim 21, the recitation "wherein said EPS increases the stability" renders the claim indefinite because it is not clear what is encompassed by the term "stability", i.e. color stability, microbial stability.

Regarding claim 26, the recitation "capable of improving at least one of the texture, aroma, flavor.. of the cheese product" renders the claim indefinite because it is unclear how this accomplished and what the properties of the cheese product are being compared.

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - Determining the scope and contents of the prior art.
  - Ascertaining the differences between the prior art and the claims at issue.
  - Resolving the level of ordinary skill in the pertinent art.
  - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- Claims 1-3, 6-12, 16-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry et al. ("Effect of Exopolysaccharide-Producing Cultures on Moisture Retention in Low Fat Mozzarella Cheese").

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Regarding claims 1-3, Perry et al. disclose a starter culture composition for making cheese comprising *Streptococcus thermophilus MR-1C* and *Lactobacillus delbrueckii MR-1R* (Abstract, p.800/Materials and Methods/Milk and Cultures).

Given Perry et al. disclose lactic acid bacterium, Streptococcus thermophilus MR-1C and Lactobacillus delbrueckii MR-1R that are capable of producing an exopolysaccharide (EPS) (Abstract, p.799/Introduction/paragraph 3), it is clear that they intrinsically are capable of producing an enzyme that is capable of producing EPS and fermenting lactic acid. Further, given Perry et al. disclose Streptococcus thermophilus, since Streptococcus thermophilus strains are known to produce EPS (Abstract, p.799/Introduction/paragraph 3), it follows that the Streptococcus thermophilus MR-1C disclosed by Perry et al. and Streptococcus thermophilus V3 could be used interchangeably.

Regarding the method limitations recited in claims 6-8, it is noted that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in *Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.). In this case, claim 1 requires a composition comprising an EPS fermentation culture which contains a viable lactic acid microorganism capable of producing EPS. In this case, Perry et al. disclose a composition identical to that presently claimed.

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Regarding claims 9 and 12, Perry et al. disclose all of the claim limitations as set forth above. Given Perry et al. disclose a composition identical to that presently claimed wherein the lactic acid bacterium is capable of producing EPS, since claim 1 does not require EPS as part of the composition, the limitations of claims 9 and 12 have been met.

Regarding claim 10, Perry et al. disclose all of the claim limitations as set forth above. While Perry et al. disclose *Streptococcus thermophilus* TA061, the reference does not explicitly disclose the V3 strain. However, given Perry et al. disclose the TA061 strain produces EPS, it would have been obvious to one of ordinary skill in the art to have used any strain of *Streptococcus thermophilus* known to produce EPS, including the V3 strain, and arrive at the present invention.

Regarding claim 11, Perry et al. disclose all of the claim limitations as set forth above. Perry et al. also disclose an adjunct culture comprising EPS producing *Lactococcus lactis ssp. Cremoris*. While Perry disclose Lactococcus lactis ssp. Cremoris, the reference does not explicitly disclose the 322 strain. However, given Perry et al. disclose *Lactococcus lactis ssp. Cremoris* produces EPS, it would be obvious to one of ordinary skill in the art to have used any strain of *Lactococcus lactis ssp. Cremoris* known to produce EPS, including the 322 strain, and arrive at the present invention.

Regarding claim 16, Perry et al. disclose a method of forming a Mozzarella cheese comprising adding the composition of claim 1 to milk, forming a cheese curd (p.800/Manufacturing Procedure). Perry et al. also disclose a ripened cheese product with about 60% moisture (p.800/Table 1/Starter 4).

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Given Perry et al. disclose lactic acid bacterium, Streptococcus thermophilus MR-1C and Lactobacillus delbrueckii MR-1R that are capable of producing an exopolysaccharide (EPS) it is clear that the bacterium, i.e. starter culture, would intrinsically produce an enzyme that produces EPS.

Regarding claims 17-18, Perry et al. disclose all of the claim limitations as set forth above. Further, Perry et al. disclose low fat Mozzarella cheese prepared using the composition of claim 1 (Abstract, p.800-801/Manufacturing Procedure & Cheese Analysis).

Regarding claims 19, Perry et al. disclose all of the claim limitations as set forth above and that the EPS cultures are useful to increase moisture retention in low fat Mozzarella cheese (p.804/Conclusions).

Regarding claims 20-21, 23 and 26, Perry et al. disclose all of the claim limitations as set forth above. Given Perry et al. disclose a process and starter culture identical to that presently claimed, it is clear that the recited process attributes and improved sensory, nutrition, and/or physical properties would intrinsically be displayed.

Regarding claims 24-25, Perry et al. disclose all of the claim limitations as set forth above. Given Perry et al. disclose a process for making cheese identical to that presently claimed, it is clear that that the resulting cheese product would intrinsically display the recited moisture level and moisture loss.

Regarding claim 27, Perry et al. disclose a method of forming a Mozzarella cheese comprising adding the composition of claim 1 to milk, forming a cheese curd (p.800/Manufacturing Procedure). Perry et al. also disclose a ripened cheese product with about 60% moisture (p.800/Table 1/Starter 4). Given Perry et al. disclose a method for forming

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Mozzarella cheese using a composition identical to that presently claimed, it is clear that the cheese curd would intrinsically contain about 50% moisture and lose less that 5% moisture as a result of ripening.

Regarding claim 28, Perry et al. disclose all of the claim limitations as set forth above and a cheese product (Abstract, p.801/Manufacturing Procedure).

Regarding claims 30, Perry et al. disclose all of the claim limitations as set forth above. Perry et al. also disclose a process for in situ production of EPS comprising providing a starter culture composition according to claim 1, inoculating vats of milk with the starter culture composition and ripening (i.e. permitting the growth of the microorganisms). Given Perry et al. disclose EPS forming microorganisms identical to those of the present invention, it is clear that the microorganisms would intrinsically produce EPS.

9. Claims 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry et al. ("Effect of Exopolysaccharide-Producing Cultures on Moisture Retention in Low Fat Mozzarella Cheese") and further in view of Degeest et al. ("Exopolysaccharide (EPS) biosynthesis by Lactobacillus sakei 0-1: production kinetics, enzyme activities and EPS yields").

Regarding claims 14 and 32, Perry et al. disclose all of the claim limitations as set forth above. While Perry disclose EPS producing lactic acid bacterium, Streptococcus thermophilus and Lactobacillus delbrueckii, the reference does not explicitly disclose a culture selected from the recited group.

Degreest et al. teach that *Lactobacillus sakei* strains are known producers of EPS in food systems (p. 470-471/Abstract, Introduction).

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Perry et al. and Degeest et al. are combinable because they are concerned with the same field of endeavor, namely, EPS producing lactic acid bacterium. Given Degeest et al. teach that Lactobacillus sakei strains are known producers of EPS, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any EPS producing lactic acid bacterium, including Lactobacillus sakei, and arrive at the present invention.

Regarding strain, while Degeest et al. teach Lactobacillus sakei 0-1, the reference does not explicitly disclose the 570 strain. However, given Degeest et al. teach the 0-1 strain produces EPS, it would have been obvious to one of ordinary skill in the art to have used any strain of Lactobacillus sakei known to produce EPS, including the 570 strain, and arrive at the present invention.

10. Claim 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry et al. ("Effect of Exopolysaccharide-Producing Cultures on Moisture Retention in Low Fat Mozzarella Cheese") and further in view of Tallgren et al. ("Exopolysaccharide-Producing Bacteria from Sugar Beets").

Regarding claims 15 and 31, Perry et al. disclose all of the claim limitations as set forth above. While Perry disclose EPS producing lactic acid bacterium, Streptococcus thermophilus and Lactobacillus delbrueckii, the reference does not explicitly disclose Leuconostoc mesenteroides or a bacterium that produces a homo-EPS.

Tallgren et al. teach that *Leuconostoc mesenteroides* strains are known producers of EPS (p. 862/Abstract, Introduction). Given Tallgren et al. teach *Leuconostoc mesenteroides*, it is clear that the bacterium would intrinsically produce a homo-EPS.

Perry et al. and Tallgren et al. are combinable because they are concerned with the same field of endeavor, namely, EPS producing lactic acid bacterium. Given Tallgren et al. teach that Leuconostoc mesenteroides strains are known producers of EPS, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any EPS producing lactic acid bacterium, including Leuconostoc mesenteroides, and arrive at the present invention.

Regarding strain, while Tallgren et al. teach 2 different Leuconostoc mesenteroides strains, the reference does not explicitly disclose the 808. However, given Tallgren et al. teach the strains produce EPS, it would have been obvious to one of ordinary skill in the art to have used any strain of Leuconostoc mesenteroides known to produce EPS, including the 808 strain, and arrive at the present invention.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Degeest et al.
 ("Exopolysaccharide (EPS) biosynthesis by Lactobacillus sakei 0-1: production kinetics, enzyme activities and EPS yields").

Regarding claim 37, Degeest et al. disclose a culture of Lactobacillus sakei 0-1 (p. 471/Materials and Methods). Given Degeest et al. disclose a Lactobacillus sakei culture, since Lactobacillus sakei strains are known to produce EPS (p.470-471/Abstract, Introduction), it follows that the Lactobacillus sakei 0-1 and Lactobacillus sakei DSM 15889 are interchangeable.

### Response to Arguments

 Applicant's arguments filed March 3, 2010 have been fully considered but they are not persuasive.

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### Rejection of claims under 35 U.S.C.§ 112, second paragraph-

Regarding claim 20, applicants argue that the specification provides a number of teachings such that a person of ordinary skill in the art would understand the phrase "capable of being achieved" and "optimizing." Specifically, applicants explain that the target moisture level in the cheese may be achieved by retarding whey release during the cheese curd curing process and that by varying the amount and type of EPS present in the curd, the moisture level may be modulated in the "tapping of or dripping off" stage. Thus applicants argue that is would be clear to a person of ordinary skill in the art that whey optimization can be achieved by varying the amount and type of EPS used.

Here, it is not clear what steps or how the whey optimization is achieved. Given there is more than one way to optimize whey release during curd processing, the claim is indefinite.

Regarding claim 21, applicants argue that the specification, p.11, lines 19 to 21, explains the phrase "increases the stability" as the stability of the cheese curd to physical manipulations.

While the specification discusses the increase in the stability of the cheese curd to physical manipulations, the specification does not explicitly define the term "stability." Given, when discussing cheese products and microorganisms, the term "stability" encompasses more than one interpretation or definition, claim 21 is indefinite. Further, there is no antecedent basis for the term "said curd."

Regarding claim 26, applicants argue that it would be clear to a person of ordinary skill in the art that a comparison would be made to a control (i.e. with a process of making cheese where the composition of claim 1 is not added.).

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It is the Examiner's position that this comparison is not clear. The comparison sample could include an ingredient that the inventive sample does not. Further, it is not clear what properties are encompassed by "improved" texture, aroma, flavour, mildness, consistency, body, mouthfeel, firmness, viscosity, gel fracture, wheying off, syneresis, structure and/or organoleptic properties, nutrition and/or health benefits of the cheese product.

# Rejection of claims under 35 U.S.C. § 102(b) and.§ 103(a)-

Applicants argue that Perry does not teach composition suitable for forming cheese, the composition wherein the EPS culture contains a viable lactic acid microorganism selected from the group consisting of Streptoccoccus thermophilus VE, Lactococcus lactis ssp cremoris 322, Lactobacillus sakei 570, and Leuconostoc mesenteroides 808, wherein the lactic acid microorganism is capable of producing an enzyme, and wherein the enzyme is capable of producing an EPS.

In this case, Perry does disclose a starter culture composition for making cheese comprising *Streptococcus thermophilus MR-1C* and *Lactobacillus delbrueckii MR-1R* (Abstract, p.800/Materials and Methods/Milk and Cultures).

Given Perry et al. disclose lactic acid bacterium, Streptococcus thermophilus MR-1C and Lactobacillus delbrueckii MR-1R that are capable of producing an exopolysaccharide (EPS) (Abstract, p.799/Introduction/paragraph 3), it is clear that they intrinsically are capable of producing an enzyme that is capable of producing EPS and fermenting lactic acid. Further, given Perry et al. disclose Streptococcus thermophilus, since Streptococcus thermophilus strains are known to produce EPS (Abstract, p.799/Introduction/paragraph 3), absent evidence to the

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contrary, it follows that the Streptococcus thermophilus MR-IC disclosed by Perry et al. and Streptococcus thermophilus V3 could be used interchangeably.

#### Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./ Examiner, Art Unit 1781

/Keith D. Hendricks/ Supervisory Patent Examiner, Art Unit 1781